

Remarks/Arguments:

This is a reply to the office action of January 13, 2005, in which the examiner withdrew rejections based on anticipation under 35 USC 102, but rejected all the claims under consideration (15 - 34) on the ground of obviousness.

Three claims have been amended above by supplying omitted periods.

We respectfully traverse the rejections under 35 USC 103. The examiner has relied on a combination of seven references. While there is no limit to the number of references that can be used in making an obviousness rejection, the need to cite a large number of references against a particular claim suggests non-obviousness.

The examiner relied particularly on Koji (JP 11-92385). We have only the English abstract, in which there is no reference whatsoever to an effervescent preparation. That Koji suggests administering a glucosamine compound in a drinking formulation is undisputed, but Koji, even in appropriate combination with the other references, does not suggest the present invention. In Koji, there is no disclosure whatsoever of glucosamine sulphate or a mixed salt thereof, or of an effervescent preparation.

In our last submission – which was accompanied by an Affidavit the examiner has not acknowledged – we explained the subject matter of the present application and how it is distinguished from Demopoulos, and why Demopoulos neither anticipates nor renders obvious to subject matter of the claims on file. Inasmuch as Demopoulos does not disclose an effervescent preparation of glucosamine sulphate, it cannot overcome the deficiencies of Koji.

The next two references, Schleck and Rovati, are related to the preparation of specific glucosamine salts. The present applicant does not claim to have provided a new

glucosamine salt, or to have discovered that mixed salts are more stable than glucosamine sulfate. To the contrary, the present invention is based on the availability of those salts as starting materials. Significantly, neither Schleck and Rovati suggests incorporating their respective salts into effervescent preparations.

The examiner's interpretation of the Merck manual citation is not disputed, but it does not cure the above-noted deficiencies of the other references.

Finally, the examiner has relied on Chiesi and Stephan. Those references are related to effervescent preparations in general. Again, we do not deny that effervescent preparations have been known in the art for a long time.

The question of obviousness turns not on whether effervescent preparations generally, and glucosamine-containing compounds generally, were known in the art; rather, it turns on whether the prior art suggests formulating glucosamine sulphate or a mixed salt thereof in an effervescent preparation. It may be noted that Rovati, which describes the preparation of a mixed glucosamine salt, was published in 1972. But in the thirty-three years since then, apparently no one has disclosed or suggested formulating glucosamine sulphate or a mixed salt thereof in an effervescent preparation. Indeed, no motivation to do so can be found in the prior art, despite the fact that it is has long been desirable to provide large amounts of glucosamine sulphate in a single formulation in order to obtain a once-a-day preparation.


It was previously known that by using effervescent preparations, a large amount of a drug can be administered at one time. However, there was a reason why no one suggested taking that approach with glucosamine sulphate. Glucosamine sulphate is a highly hygroscopic and unstable substance. As described on the first page of the present specification, this is the reason why glucosamine sulphate was previously provided in coated formulations which protect the substance from oxygen. There was

no indication in the prior art that glucosamine sulphate could be stably provided in an effervescent preparation. To the contrary, it would have been reasonable to assume that in an effervescent preparation the above problems would even increase: effervescent preparations are generally hygroscopic, which should have a negative influence on the stability of the glucosamine sulphate.

In summary, it was unexpected and surprising that glucosamine sulphate and its mixed salts could nevertheless be provided in a storage-stable form and in large amounts in an effervescent tablet. With respect, it appears the reasoning leading to the rejections is largely based on hindsight and does not fairly indicate the motivation a person skilled in the art at the time the invention was made would actually have had. For example, it is interesting to note that both in Chiesi and Stephan – which are related to effervescent preparations – there is no suggestion that one might use glucosamine sulphate as an active ingredient.

In summary, we believe that the subject matter of the claims on file is not rendered obvious by the prior art cited by the examiner, and that claims 15 - 34 are patentable over the prior art of record.

Respectfully submitted, -



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I certify that this correspondence is being transmitted by facsimile on March 16, 2005, to the Patent and Trademark Office at 703.872.9306.

